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PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

19 IN RE BEXTRA AND CELEBREX ) MDL Docket No. 1699  
20 MARKETING, SALES PRACTICES AND ) CASE NO. 3:08-cv-0977-CRB  
21 PRODUCTS LIABILITY LITIGATION )  
22 *This document relates to* ) PFIZER INC., PHARMACIA  
23 OLIVE BEEBE, et al., ) CORPORATION, AND G.D.  
24 Plaintiffs, ) SEARLE LLC'S ANSWER TO  
25 vs. ) COMPLAINT  
26 PFIZER, INC., PHARMACIA CORPORATION, ) JURY DEMAND ENDORSED  
27 G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.), ) HEREIN  
and MONSANTO COMPANY, )  
Defendants. )

2 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
3 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"<sup>1</sup>)  
4 ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file their  
5 Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as  
follows:

I.

## **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used  
9 Celebrex® (celecoxib) (“Celebrex®”). Accordingly, this Answer can only be drafted  
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the  
11 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

II.

## ANSWER

## **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but  
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,  
21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by  
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used

25       <sup>1</sup> Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known  
26       as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933  
27       Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag  
28       Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its  
name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and  
does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that  
Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing Celebrex®, *see PLAINTIFFS' COMPLAINT at ¶ 7*, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As a result,  
Pharmacia will respond to the allegations directed at Monsanto Company.

1 in accordance with its FDA-approved prescribing information. Defendants state that the  
2 potential effects of Celebrex® were and are adequately described in its FDA-approved  
3 prescribing information, which was at all times adequate and comported with applicable  
4 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
5 Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 2. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
11 and deny the remaining allegations in this paragraph of the Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
14 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
16 and deny the remaining allegations in this paragraph of the Complaint.

17 4. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
19 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
21 and deny the remaining allegations in this paragraph of the Complaint.

22 5. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
23 business in New York. Defendants admit that, as the result of a merger in April 2003,  
24 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
25 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants  
26 are without knowledge or information sufficient to form a belief as to the truth of such  
27 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
28 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to

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1 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
2 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
3 paragraph of the Complaint.

4 6. Defendants admit that Searle is a Delaware limited liability company with its principal  
5 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,  
6 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
7 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
8 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
9 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
11 the remaining allegations in this paragraph of the Complaint.

12 7. Defendants admit that in 1933 an entity known as Monsanto Company (“1933  
13 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of  
14 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name  
15 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,  
16 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company  
17 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged  
18 in the agricultural business and does not and has not ever manufactured, marketed, sold, or  
19 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either  
20 Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed,  
21 sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a  
22 proper party in this matter. Defendants deny the remaining allegations in this paragraph of the  
23 Complaint. Defendants state that the response to this paragraph of the Complaint regarding  
24 Monsanto is incorporated by reference into Defendants’ responses to each and every paragraph  
25 of the Complaint referring to Monsanto and/or Defendants.

26 8. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
27 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
28 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.

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1 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
2 Celebrex® in the United States, including California, to be prescribed by healthcare providers  
3 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Allegations Regarding Jurisdiction and Venue**

6 9. Defendants are without knowledge or information to form a belief as to the truth of the  
7 allegations in this paragraph of the Complaint regarding the amount in controversy, and,  
8 therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount  
9 in controversy exceeds \$75,000, exclusive of interests and costs.

10 10. Defendants are without knowledge or information to form a belief as to the truth of the  
11 allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount  
12 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim  
13 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of  
14 interests and costs.

15 11. Defendants are without knowledge or information to form a belief as to the allegations  
16 in this paragraph of the Complaint regarding the judicial district in which the asserted claims  
17 allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe  
18 and effective when used in accordance with its FDA-approved prescribing information.  
19 Defendants deny committing a tort in the States of California, Washington, Mississippi, and  
20 Montana, and deny the remaining allegations in this paragraph of the Complaint.

21 12. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
22 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
23 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
24 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
25 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
26 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
27 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
28 that Pfizer, Pharmacia, and Searle are registered to and do business in the State of California.

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1 Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors  
2 in interest" are vague and ambiguous. Defendants are without knowledge or information  
3 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.  
4 Defendants deny committing a tort in the States of California, Washington, Mississippi, and  
5 Montana, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Allegations Regarding Interdistrict Assignment**

7 13. Defendants state that this paragraph of the Complaint contains legal contentions to  
8 which no response is required. To the extent that a response is deemed required, Defendants  
9 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
10 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
11 Panel on Multidistrict Litigation on September 6, 2005.

12 **Response to Factual Allegations**

13 14. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
16 effective when used in accordance with its FDA-approved prescribing information. Defendants  
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
18 approved prescribing information, which was at all times adequate and comported with  
19 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
20 Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this  
21 paragraph of the Complaint.

22 15. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
24 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,  
25 Celebrex® was expected to reach users and consumers without substantial change from the  
26 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 16. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used

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1 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
2 effective when used in accordance with its FDA-approved prescribing information. Defendants  
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
4 approved prescribing information, which was at all times adequate and comported with  
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
6 remaining allegations in this paragraph of the Complaint.

7 17. Defendants state that the allegations in this paragraph of the Complaint regarding  
8 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
9 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
10 referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the  
11 remaining allegations in this paragraph of the Complaint.

12 18. Defendants state that the allegations in this paragraph of the Complaint are not directed  
13 towards Defendants and, therefore, no response is required. To the extent that a response is  
14 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
15 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
16 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

17 19. Defendants state that the allegations in this paragraph of the Complaint are not directed  
18 towards Defendants and, therefore, no response is required. To the extent that a response is  
19 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
20 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
21 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22 19. Answering the second Paragraph 19 of the Complaint, Defendants state that the  
23 allegations in this paragraph of the Complaint are not directed towards Defendants and,  
24 therefore, no response is required. To the extent that a response is deemed required, Defendants  
25 state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
26 Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as  
27 to the truth of such allegations and, therefore, deny the same.

28 20. Defendants state that the allegations in this paragraph of the Complaint are not directed

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1 towards Defendants and, therefore, no response is required. To the extent that a response is  
2 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
3 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
4 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

5 21. Defendants state that the allegations in this paragraph of the Complaint regarding "other  
6 pharmaceutical companies" are not directed towards Defendants and, therefore, no response is  
7 required. To the extent a response is deemed required, Defendants state that, as stated in the  
8 FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to  
9 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
10 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
11 cyclooxygenase-1 (COX-1) isoenzyme." Plaintiffs fail to provide the proper context for the  
12 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
13 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
14 allegations in this paragraph of the Complaint.

15 22. Defendants state that the allegations in this paragraph of the Complaint regarding  
16 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
17 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
18 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he  
19 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,  
20 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in  
21 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants  
22 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
23 approved prescribing information. Defendants state that the potential effects of Celebrex®  
24 were and are adequately described in its FDA-approved prescribing information, which was at  
25 all times adequate and comported with applicable standards of care and law. Defendants deny  
26 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 23. Defendants admit that Searle submitted a New Drug Application ("NDA") for  
28 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted

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1 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
2 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
3 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to  
4 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
5 ("FAP") as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny  
6 the remaining allegations in this paragraph of the Complaint.

7 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit  
8 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted  
9 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
11 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,  
12 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States  
13 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
14 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe  
15 and effective when used in accordance with its FDA-approved prescribing information.  
16 Defendants state that the potential effects of Celebrex® were and are adequately described in its  
17 FDA-approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 25. Defendants state that the referenced article speaks for itself and respectfully refer the  
21 Court to the article for its actual language and text. Any attempt to characterize the article is  
22 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
24 this paragraph of the Complaint.

25 26. Defendants state that the referenced article speaks for itself and respectfully refer the  
26 Court to the article for its actual language and text. Any attempt to characterize the article is  
27 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants deny the remaining allegations in

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1 this paragraph of the Complaint.

2 27. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny the allegations in this paragraph of the Complaint.

7 28. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 29. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
14 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
15 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
16 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
17 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
18 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
19 the Complaint.

20 30. Defendants state that the referenced Medical Officer Review speaks for itself and  
21 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
22 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
23 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court  
24 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to  
25 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining  
26 allegations in this paragraph of the Complaint.

27 31. Defendants state that the referenced study speaks for itself and respectfully refer the  
28 Court to the study for its actual language and text. Any attempt to characterize the study is

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1 denied. Defendants state that the referenced article speaks for itself and respectfully refer the  
2 Court to the article for its actual language and text. Any attempt to characterize the article is  
3 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
4 paragraph of the Complaint.

5 32. Defendants state that the referenced Medical Officer Review speaks for itself and  
6 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
7 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
8 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
9 language and text. Any attempt to characterize the article is denied. Defendants deny the  
10 remaining allegations in this paragraph of the Complaint.

11 33. Defendants state that the referenced article speaks for itself and respectfully refer the  
12 Court to the article for its actual language and text. Any attempt to characterize the article is  
13 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
14 paragraph of the Complaint.

15 34. Defendants state that the referenced articles speak for themselves and respectfully refer  
16 the Court to the articles for their actual language and text. Any attempt to characterize the  
17 articles is denied. Defendants state that the referenced study speaks for itself and respectfully  
18 refer the Court to the study for its actual language and text. Any attempt to characterize the  
19 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 35. Defendants state that the referenced Medical Officer Review speaks for itself and  
21 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
22 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
23 allegations in this paragraph of the Complaint.

24 36. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
25 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
26 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 37. Defendants state that the referenced study speaks for itself and respectfully refer the

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1 Court to the study for its actual language and text. Any attempt to characterize the study is  
2 denied. Plaintiffs fail to provide the proper context for the allegations concerning "Public  
3 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
4 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 38. Defendants admit that there was a clinical trial called APC. Defendants state that the  
7 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
8 language and text. Any attempt to characterize the article is denied. Defendants deny the  
9 remaining allegations in this paragraph of the Complaint.

10 39. Defendants admit that there was a clinical trial called APC. Defendants state that the  
11 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
12 language and text. Any attempt to characterize the article is denied. Defendants deny the  
13 remaining allegations in this paragraph of the Complaint.

14 40. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
15 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
16 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 41. Defendants state that the referenced Medical Officer Review speaks for itself and  
19 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
20 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
21 allegations in this paragraph of the Complaint.

22 42. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide  
23 the proper context for the allegations concerning "other Celebrex trials" contained in this  
24 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
25 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
26 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
27 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
28 actual language and text. Any attempt to characterize the study is denied. Defendants deny the

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1 remaining allegations in this paragraph of the Complaint.

2 43. Defendants state that the referenced article speaks for itself and respectfully refer the  
3 Court to the article for its actual language and text. Any attempt to characterize the article is  
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 44. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
6 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
7 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
8 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for  
9 themselves and respectfully refer the Court to the studies for their actual language and text.  
10 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
11 this paragraph of the Complaint.

12 45. Defendants state that the referenced Medical Officer Review speaks for itself and  
13 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
14 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
15 allegations in this paragraph of the Complaint.

16 46. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®  
17 in this paragraph of the Complaint are not directed toward Defendants, and therefore no  
18 response is required. To the extent that a response is deemed required, Plaintiffs fail to provide  
19 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in  
20 this paragraph of the Complaint. Defendants therefore lack sufficient information or  
21 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
22 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
23 the study for its actual language and text. Any attempt to characterize the study is denied.  
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 47. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
26 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
27 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
28 fail to provide the proper context for the allegations in this paragraph of the Complaint

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1 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
2 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
3 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
4 respectfully refer the Court to the study for its actual language and text. Any attempt to  
5 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
6 the Complaint.

7 48. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
8 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
9 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
10 fail to provide the proper context for the allegations in this paragraph of the Complaint  
11 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
12 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
13 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
14 respectfully refer the Court to the study for its actual language and text. Any attempt to  
15 characterize the study is denied. Defendants state that the referenced article speaks for itself  
16 and respectfully refer the Court to the article for its actual language and text. Any attempt to  
17 characterize the article is denied. Defendants deny the remaining allegations in this paragraph  
18 of the Complaint.

19 49. Defendants state that Celebrex® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants deny the allegations in this  
21 paragraph of the Complaint.

22 50. Defendants state that the referenced article speaks for itself and respectfully refer the  
23 Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 51. Defendants state that allegations in this paragraph of the Complaint are not directed  
26 toward Defendants, and therefore no response is required. To the extent that a response is  
27 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
28 refer the Court to the article for its actual language and text. Any attempt to characterize the

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1 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 52. Defendants deny the allegations in this paragraph of the Complaint.

3 53. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
8 remaining allegations contained in this paragraph of the Complaint.

9 54. Defendants deny any wrongful conduct and deny the allegations contained in this  
10 paragraph of the Complaint.

11 55. Defendants deny any wrongful conduct and deny the allegations contained in this  
12 paragraph of the Complaint.

13 56. Defendants state that Celebrex® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
18 paragraph of the Complaint.

19 57. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
26 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 58. Defendants admit that the FDA Division of Drug Marketing, Advertising, and

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1 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
2 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
3 actual language and text. Any attempt to characterize the letter is denied. Defendants admit  
4 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
5 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual  
6 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
7 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
8 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to  
9 characterize the transcripts is denied. Defendants state that the referenced study speaks for  
10 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
11 to characterize the article is denied. Defendants deny the remaining allegations in this  
12 paragraph of the Complaint.

13 59. Defendants state that Celebrex® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
18 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
19 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
20 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
21 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
22 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
23 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
24 allegations in this paragraph of the Complaint.

25 60. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
2 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
3 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
4 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
5 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
6 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
7 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a  
8 prescription medication which is approved by the FDA for the following indications: (1) for  
9 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
10 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
11 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
12 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
13 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
14 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
15 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this  
16 paragraph of the Complaint.

17 61. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which at all times was adequate and comported with applicable standards of care and law.  
21 Defendants state that Plaintiffs' allegations in this paragraph of the Complaint regarding  
22 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
23 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
24 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
25 allegations in this paragraph of the Complaint.

26 62. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
3 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
4 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
5 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
6 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
7 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
8 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
9 allegations in this paragraph of the Complaint.

10 63. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which at all times was adequate and comported with applicable standards of care and law.  
14 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
15 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
16 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
17 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
18 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
19 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
20 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
21 allegations in this paragraph of the Complaint.

22 64. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 65. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
5 the Complaint.

6 66. Defendants deny the allegations in this paragraph of the Complaint.

7 67. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 68. Defendants state that Celebrex® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
16 which was at all times adequate and comported with applicable standards of care and law.  
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
18 the Complaint.

19 69. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
21 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
22 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
23 paragraph of the Complaint.

24 70. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the

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1 remaining allegations in this paragraph of the Complaint.

2 71. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 72. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
13 the study for its actual language and text. Any attempt to characterize the study is denied.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint.

16 73. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
19 effective when used in accordance with its FDA-approved prescribing information. Defendants  
20 state that the potential effects of Celebrex® are and were adequately described in its FDA-  
21 approved prescribing information, which was at all times adequate and comported with  
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
23 remaining allegations in this paragraph of the Complaint.

24 **Response to First Cause of Action: Negligence**

25 74. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
26 Complaint as if fully set forth herein.

27 75. Defendants state that this paragraph of the Complaint contains legal contentions to  
28 which no response is required. To the extent that a response is deemed required, Defendants

1 admit that they had duties as are imposed by law but deny having breached such duties.  
2 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
3 FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 76. Defendants state that this paragraph of the Complaint contains legal contentions to  
9 which no response is required. To the extent that a response is deemed required, Defendants  
10 admit that they had duties as are imposed by law but deny having breached such duties.  
11 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
12 FDA-approved prescribing information. Defendants state that the potential effects of  
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.  
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
16 the Complaint

17 77. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
22 the Complaint, including all subparts.

23 78. Plaintiff's Complaint omits Paragraph 78.

24 79. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
3 remaining allegations in this paragraph of the Complaint.

4 80. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 81. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
13 effective when used in accordance with its FDA-approved prescribing information. Defendants  
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
15 approved prescribing information, which was at all times adequate and comported with  
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
17 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
18 paragraph of the Complaint.

19 82. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
21 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
22 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
23 paragraph of the Complaint.

24 83. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 84. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28

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## **Response to Second Cause of Action: Strict Liability**

85. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

86. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

88. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
4 remaining allegations in this paragraph of the Complaint, including all subparts.

5 90. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny that Celebrex® is unreasonably dangerous and deny the remaining allegations  
10 in this paragraph of the Complaint.

11 91. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
18 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 92. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
25 remaining allegations in this paragraph of the Complaint.

26 93. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants  
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
3 approved prescribing information, which was at all times adequate and comported with  
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
5 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the  
6 remaining allegations in this paragraph of the Complaint.

7 94. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 95. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
16 effective when used in accordance with its FDA-approved prescribing information. Defendants  
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
18 approved prescribing information, which was at all times adequate and comported with  
19 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
20 Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
21 paragraph of the Complaint.

22 96. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 97. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
3 effective when used in accordance with its FDA-approved prescribing information. Defendants  
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
7 remaining allegations in this paragraph of the Complaint.

8 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 99. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 100. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 **Response to Third Cause of Action: Breach of Express Warranty**

15 101. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
16 Complaint as if fully set forth herein.

17 102. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
20 effective when used in accordance with its FDA-approved prescribing information. Defendants  
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
22 approved prescribing information, which was at all times adequate and comported with  
23 applicable standards of care and law. Defendants admit that they provided FDA-approved  
24 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
25 this paragraph of the Complaint.

26 103. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

1 effective when used in accordance with its FDA-approved prescribing information. Defendants  
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
3 approved prescribing information, which was at all times adequate and comported with  
4 applicable standards of care and law. Defendants admit that they provided FDA-approved  
5 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and  
6 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

7 104. Defendants admit that they provided FDA-approved prescribing information regarding  
8 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
9 paragraph of the Complaint.

10 105. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint.

16 106. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 107. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
24 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of  
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants admit that they provided FDA-approved prescribing information regarding  
28 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 110. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Fourth Cause of Action: Breach of Implied Warranty**

8 111. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
9 Complaint as if fully set forth herein.

10 112. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
11 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
12 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
13 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
14 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
15 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
16 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
17 the remaining allegations in this paragraph of the Complaint.

18 113. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants admit that they provided FDA-approved prescribing information regarding  
23 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 114. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 115. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
4 effective when used in accordance with its FDA-approved prescribing information. Defendants  
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
6 approved prescribing information, which was at all times adequate and comported with  
7 applicable standards of care and law. Defendants admit that they provided FDA-approved  
8 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
9 this paragraph of the Complaint.

10 116. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
12 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,  
13 Celebrex® was expected to reach users and consumers without substantial change from the  
14 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 117. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
17 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they  
22 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

23 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

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1       **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

2       121. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' 3 Complaint as if fully set forth herein.

4       122. Defendants state that this paragraph of the Complaint contains legal contentions to 5 which no response is required. To the extent that a response is deemed required, Defendants 6 admit that they had duties as are imposed by law but deny having breached such duties. 7 Defendants state that Celebrex® was and is safe and effective when used in accordance with its 8 FDA-approved prescribing information. Defendants state that the potential effects of 9 Celebrex® were and are adequately described in its FDA-approved prescribing information, 10 which was at all times adequate and comported with applicable standards of care and law. 11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of 12 the Complaint.

13       123. Defendants state that Celebrex® was and is safe and effective when used in accordance 14 with its FDA-approved prescribing information. Defendants state that the potential effects of 15 Celebrex® were and are adequately described in its FDA-approved prescribing information, 16 which was at all times adequate and comported with applicable standards of care and law. 17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of 18 the Complaint, including all subparts.

19       124. Defendants state that Celebrex® was and is safe and effective when used in accordance 20 with its FDA-approved prescribing information. Defendants state that the potential effects of 21 Celebrex® were and are adequately described in its FDA-approved prescribing information, 22 which was at all times adequate and comported with applicable standards of care and law. 23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of 24 the Complaint.

25       125. Defendants are without knowledge or information sufficient to form a belief as to the 26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used 27 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and 28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
2 approved prescribing information, which was at all times adequate and comported with  
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
4 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this  
5 paragraph of the Complaint.

6 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 127. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
15 effective when used in accordance with its FDA-approved prescribing information. Defendants  
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
17 approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 128. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
27 remaining allegations in this paragraph of the Complaint.

28 129. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
2 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
3 effective when used in accordance with its FDA-approved prescribing information. Defendants  
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
7 remaining allegations in this paragraph of the Complaint.

8 130. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
11 effective when used in accordance with its FDA-approved prescribing information. Defendants  
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
13 approved prescribing information, which was at all times adequate and comported with  
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 131. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
19 effective when used in accordance with its FDA-approved prescribing information. Defendants  
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
21 approved prescribing information, which was at all times adequate and comported with  
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
23 remaining allegations in this paragraph of the Complaint.

24 132. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
3 remaining allegations in this paragraph of the Complaint.

4 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Sixth Cause of Action: Unjust Enrichment**

11 136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 137. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
20 the remaining allegations in this paragraph of the Complaint.

21 138. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
23 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
24 paragraph of the Complaint.

25 139. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
27 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
28 paragraph of the Complaint.

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1 140. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
3 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
4 effective when used in accordance with its FDA-approved prescribing information. Defendants  
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
6 approved prescribing information, which was at all times adequate and comported with  
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
8 remaining allegations in this paragraph of the Complaint.

9 141. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
11 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
16 remaining allegations in this paragraph of the Complaint.

17 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Prayer for Relief**

20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
21 damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for  
22 Relief," including all subparts.

23 **III.**

24 **GENERAL DENIAL**

25 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'  
26 Complaint that have not been previously admitted, denied, or explained.

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IV.

## **AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

## First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

## **Second Defense**

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

### **Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

## **Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

## **Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

## **Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.

## **Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

## **Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

## **Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

## **Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

## **Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

## **Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

## Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the

1 time it left the control of the manufacturer or seller.

2 **Fourteenth Defense**

3 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit  
4 for its intended use and the warnings and instructions accompanying Celebrex® at the time of  
5 the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved  
6 usages.

7 **Fifteenth Defense**

8 15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the  
9 Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable  
10 standard of care.

11 **Sixteenth Defense**

12 16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of  
13 the product Celebrex® after the product left the control of Defendants and any liability of  
14 Defendants is therefore barred.

15 **Seventeenth Defense**

16 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of  
17 Defendants.

18 **Eighteenth Defense**

19 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent  
20 conditions unrelated to Celebrex®.

21 **Nineteenth Defense**

22 19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore,  
23 the doctrine of assumption of the risk bars or diminishes any recovery.

24 **Twentieth Defense**

25 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are  
26 preempted in accordance with the Supremacy Clause of the United States Constitution and by  
27 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

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## Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

## **Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

## **Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

## **Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

## Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

## Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

## **Twenty-seventh Defense**

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

## Twenty-eighth Defense

2 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
3 Products Liability.

## Twenty-ninth Defense

5 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead  
6 facts sufficient under the law to justify an award of punitive damages.

## **Thirtieth Defense**

8 30. Defendants affirmatively aver that the imposition of punitive damages in this case  
9 would violate Defendants' rights to procedural due process under both the Fourteenth  
10 Amendment of the United States Constitution and the Constitutions of the States of California,  
11 Washington, Mississippi, and Montana, and would additionally violate Defendants' rights to  
12 substantive due process under the Fourteenth Amendment of the United States Constitution.

## **Thirty-first Defense**

14 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and  
15 Fourteenth Amendments to the United States Constitution.

## **Thirty-second Defense**

17 32. The imposition of punitive damages in this case would violate the First Amendment to  
18 the United States Constitution.

### **Thirty-third Defense**

20 | 33. Plaintiffs' punitive damage claims are preempted by federal law.

## **Thirty-fourth Defense**

22 34. In the event that reliance was placed upon Defendants' nonconformance to an express  
23 representation, this action is barred as there was no reliance upon representations, if any, of  
24 Defendants.

## **Thirty-fifth Defense**

26 35. Plaintiffs failed to provide Defendants with timely notice of any alleged  
27 nonconformance to any express representation.

## **Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

### **Thirty-seventh Defense**

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

## Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California, Washington, Mississippi, and Montana. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks

1 constitutionally sufficient standards for appellate review of punitive damages awards; and (8)  
 2 otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific*  
 3 *Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources,*  
 4 *Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State*  
 5 *Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
 8 and marketing of Celebrex®, if any, used in this case, included adequate warnings and  
 9 instructions with respect to the product's use in the package insert and other literature, and  
 10 conformed to the generally recognized, reasonably available, and reliable state of the  
 11 knowledge at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Celebrex® was designed,  
 14 tested, manufactured and labeled in accordance with the state-of-the-art industry standards  
 15 existing at the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
 18 information and belief, such injuries and losses were caused by the actions of persons not  
 19 having real or apparent authority to take said actions on behalf of Defendants and over whom  
 20 Defendants had no control and for whom Defendants may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
 23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
 24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,  
 27 waiver, and/or estoppel.

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## **Forty-fourth Defense**

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

## **Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

## **Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

## **Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

## Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

## Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

## **Fiftieth Defense**

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

## **Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

## Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

## Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs’ claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs’ claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

## **Fifty-fourth Defense**

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

## Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

**Fifty-sixth Defense**

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

**Fifty-seventh Defense**

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

**Fifty-eighth Defense**

58. Defendants plead the applicability of the Washington Products Liability Act, RCW 7.72 et seq., and specifically aver that Plaintiffs' common law claims are preempted by the statute and must be dismissed.

**Fifty-ninth Defense**

59. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs' claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiffs failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

**Sixtieth Defense**

60. Any verdict or judgment rendered against Defendants must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs and any such parties.

**Sixty-first Defense**

61. Plaintiffs' claims for punitive damages are limited or barred by the standards governing

1 exemplary damage awards which arise under the United States Constitution and decisions of  
 2 the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589  
 3 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and  
 4 *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi  
 5 Constitution, statutes, and decisions of Mississippi courts.

6 **Sixty-second Defense**

7 62. Defendants assert that Plaintiffs' claim for punitive damages is governed and limited by  
 8 Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the  
 9 same.

10 **Sixty-third Defense**

11 63. Celebrex® and the Defendants' actions conformed to the state of the art medical and  
 12 scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with  
 13 applicable product safety statutes and regulations as described in Restatement (Third) of Torts:  
 14 Products Liability § 4.

15 **Sixty-fourth Defense**

16 64. Defendants satisfied their duty to warn under the learned intermediary doctrine and  
 17 Plaintiffs' claims are therefore barred.

18 **Sixty-fifth Defense**

19 65. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and  
 20 hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

21 **Sixty-sixth Defense**

22 66. Plaintiffs failed to join all indispensable parties; as a result of such failure to join,  
 23 complete relief cannot be accorded to those already parties to the action and will result in  
 24 prejudice to Defendants in any possible future litigation.

25 **Sixty-seventh Defense**

26 67. Any judicially-created definitions of manufacturing defect and design defect, and  
 27 standards for determining whether there has been an actionable failure to ward, are  
 28 unconstitutional in that, among other things, they are void for vagueness and undue burden on

1 interstate commerce, as well as an impermissible effort to regulate in an area that previously has  
2 been preempted by the federal government.

## **Sixty-eighth Defense**

4 68. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of  
5 Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any  
6 award of punitive damages is barred.

## **Sixty-ninth Defense**

8 69. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring  
9 such claims.

## **Seventieth Defense**

1 70. Defendants reserve the right to supplement their assertion of defenses as they continue  
2 with their factual investigation of Plaintiffs' claims.

V.

## PRAYER

5 WHEREFORE, Defendants pray for judgment as follows:

6 1. That Plaintiffs take nothing from Defendants by reason of the Complaint;

7 2. That the Complaint be dismissed;

8 3. That Defendants be awarded their costs for this lawsuit;

9 4. That the trier of fact determine what percentage of the combined fault or other liability  
20 of all persons whose fault or other liability proximately caused Plaintiffs' alleged  
21 injuries, losses or damages is attributable to each person;

22 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater  
23 than an amount which equals their proportionate share, if any, of the total fault or other  
24 liability which proximately caused Plaintiffs' injuries and damages; and

25 6. That Defendants have such other and further relief as the Court deems appropriate.

1 April 2, 2008

GORDON & REES LLP

8 April 2, 2008

TUCKER ELLIS & WEST LLP

11 By: \_\_\_\_\_/s/

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19 PFIZER INC., PHARMACIA  
20 CORPORATION, and G.D. SEARLE  
21 LLC

22 **Gordon & Rees, LLP**  
23 **275 Battery Street, Suite 2000**  
24 **San Francisco, CA 94111**

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a  
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil  
4 Procedure.

5 April 2, 2008

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